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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,750	10/25/2001	Jenny Louie-Helm	3100-0003	1055

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/014,750	Applicant(s) LOUIE-HELM ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 & 4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 10/25/01, supplemental IDS filed 04/07/03, request fro extension of time and response to restriction requirement filed 04/17/03.

Election/Restrictions

Examiner acknowledges the election of group I, claims 1-40 without traverse. Claims 41-44 are thus withdrawn form consideration.

Information Disclosure Statement

1. The information disclosure statement filed 04/07/03 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. It is respectfully suggested that applicants provide copies of the references, particularly the non-patent literature cited in the Form PTO-1449 submitted on 04/07/03.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-9, 12-16, 18-23, 26-32, 34 and 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389).

Shell discloses a controlled release oral dosage form that comprises drug particles dispersed in swellable/erodible polymer where the erodible polymer is polyethylene oxide; the dosage form is formulated as tablet or capsule and liposomes or nanoparticles or enteric-coated drug particles are examples of drug containing vesicles that can deliver drugs to the site of interest (abstract, column 1, line 48 to column 2 line 36, column 3, lines 26-44, column 4, lines 5-18, column 7, lines 60-62, column 8, lines 4-55). Ciprofloxacin (column 5, line 10), bismuth subsalicylate, bismuth citrate, antibiotics such as amoxicillin, tetracycline, chlarithromycin, thiamphenicol, metronidazole which are Helicobacter pylori eradicating drugs (column 5, lines 46-49 and claims 6-9), gastric lowering agents such as omeprazole, ranitidine, cimetidine, famotidine (column 5, lines 49-55) are examples of drugs delivered by the dosage form of Shell. Shell also teaches that nifedipine, acyclovir, alprazolam, phenytoin, carbamazepine, clozapne, lovastatin and nitrofurantoin are other drugs that can be delivered by the vesicle (claim 5).

The molecular weight of the polyethylene glycol in Shell ranges from 1×10^5 to 7×10^6 kD (claims 3 and 4). The weight ratio of drug to polymer is 2:3 to 9:1 (column 8, lines 26-31).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. In claim 9, the presence of a mixture of polyethylene oxide-co-propylene oxide is optional so that Shell meets the limitation of claims 1. Shell teaches a range of drug to polymer and one of the points in the taught range in Shell anticipates a point in the recited range in claims 13-16. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is

recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent and because the instant claims have not recited any drugs that would have the molecular weight recited in instant claim 21 and because some of the drugs recited in the claims are the same as those taught by Shell, Shell meets the limitations of claim 21. Therefore, the teachings of Shell meet the limitations of the claims.

4. Claims 1-7, 10, 12 and 17-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell (US 5,007,790).

Shell discloses a sustained release oral dosage form in tablet or pill and the dosage form comprises drugs and cross-linked hydrophilic and water swellable polymer (abstract, column 2, line 29 to column 3 line 15 and claims 1-9). The drugs included in the dosage form of Shell are calcium carbonate, cimetidine, ranitidine, indomethacin, ibuprofen, naproxen, prednisone, prednisolone, dexamethasone, piroxicam, aspirin, nifedipine and potassium chloride potassium supplement (column 2, lines 28-35); carboxymethyl cellulose, alginate, polyvinyl alcohol and chitin (column 3, lines 7-16) are examples of cross-linked polymer.

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent. Shell reads on the scope of the claims.

5. Claims 1-7, 10, 17-22 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Uemura et al. (US 4,695,467).

Uemura discloses sustained release tablet; the tablet comprising disintegrable granules that contain a drug, disintegrating agents selected from starch derivatives, gums, cellulose derivatives and ion exchange resins, and water soluble polymer selected from cellulose derivatives, synthetic water soluble polymers and polysaccharide and excipient (abstract, column 3, lines 10-21). The water-soluble cellulose derivatives are hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose and carboxymethylcellulose; synthetic water-soluble polymers are polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone and polyethylene oxide; and pullulan and dextran are examples of polysaccharides (column 3, lines 33-41).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent. The teaching of Uemura meets the limitations of the claims.

6. Claims 1-25, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Shell et al. (US 6,340,475).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Shell discloses a composition that comprises a swellabale polymeric matrix and a drug; and the formulation is designed for gastric retention (abstract). The composition comprises a drug dispersed in water-swellable hydrophilic polymer where the formulation erodes at a rate that is slower than the swelling rate (column 5, lines 57-66). The drug is metformin, ciprofloxacin, vancomycin, captopril, amoxicilin, paclitaxel, topiramate, ranitidine, cyclosporin or erythromycin (column 6, line 39 to column 7 line 43). Hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, polyethylene glycols, polyalkylene oxides, polyvinyl alcohol, xanthan gum (column 7, lines 58-67), hydroxypropylmethylcellulose (column 8, line 16) and cross-linked polyacrylic acid (column 8, lines 1 and 56-67) are examples of polymers that can be used in the Shell's formulation. Shell's formulation is in the form of particles, tablets and particles retained in capsules (column 9, lines 61-63). Shell discloses polyethylene oxide having molecular weight ranging form about 4,000,000 to 10,000,000 (column 8, lines 29-51) and the ratio of drug to polymer ranges from 0.01:99.999 to about 80:10 (column 10, lines 50-60). See also examples 1-10 and claims 1-89). The teachings of Shell anticipate the claims.

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. In claim 9, the presence of a mixture

of polyethylene oxide-co-propylene oxide is optional so that Shell meets the limitation of claims 1. Shell teaches a range of drug to polymer and one of the points in the taught range in Shell anticipates a point in the recited range in claims 13-16. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent. The teachings of Shell meet the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (US 5,972,389) in view of Shell et al. (US 6,340,475).

Shell (US 5,972,389) clearly teaches the tablet of capsule formulation of the instant claims. Shell in the '389 patent does not teach metformin as one of the drugs contained in the tablet or capsule. Regarding the nanocrystal or nanocapsule nature of the nanoparticle, the difference between the capsule of Shell in the '389 patent and the nanocapsule of the instant claim is one of size and differences in size does not patentably distinguish the invention from the prior art. Shell (US 6,340,475) teaches metformin in combination with hydrophilic water swellable polymer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the tablet or capsule formulation of the Shell '389 patent. One having ordinary skill in the art would have been motivated to modify the teaching

of the '389 patent by incorporating metformin in the water swellable hydrophilic polymeric tablet according to the '475 patent with the expectation that the formulation will be retained in the gastric cavity for the release of metformin in the gastric cavity.

Observation/Suggestion:

Claims 6, 7 and 10 recite "cellulosic" and the cellulose included in the "cellulosic" term is not disclosed. It is suggested that the term ---cellulose--- be used in the claims.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600